



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	391730	Calcium Plus
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	4/07/2022	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Calcium Plus

Product Type	Single Medicine Product	Effective Date	4/07/2022
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Permitted Indications

Maintain/support collagen formation

Maintain/support general health and wellbeing

Maintain/support healthy teeth

Maintain/support nail health/strength/thickness

Aid/assist/helps connective tissue production/formation

Maintain/support bone health

Aids/assists healthy bone development/growth/building

Maintain/support bone mass/density/integrity

Maintain/support bone strength

Help maintain/support bone mineralisation

A diet deficient in calcium can lead to osteoporosis in later life. Calcium may help prevent osteoporosis when dietary intake is inadequate

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life

Helps maintain/supports healthy joint cartilage growth/development/production

Maintain/support blood health

Maintain/support healthy cardiovascular system function

Maintain/support heart health

Maintain/support healthy digestive system function

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support healthy muscle contraction function

Maintain/support muscle function

Maintain/support healthy neuromuscular system/function

Maintain/support healthy ligaments

Maintain/support tendon health

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in elderly individuals

Maintain/support (state vitamin/mineral/nutrient) levels in the body



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Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate
Maintain/support (state vitamin/mineral) within normal range
Maintain/support nerve conduction
Maintain/support neuromuscular function
Maintain/support nervous system function
Maintain/support skin integrity/structure

Indication Requirements

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Indication can only be used for medicines that contain calcium as an active ingredient and the recommended daily dose of the medicine must provide at least 290 milligrams of elemental calcium.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

calcium glycinate	704.23 mg
Equivalent: calcium	150 mg
colecalfiferol	.0025 mg
colloidal anhydrous silica	21.4 mg
Equivalent: silicon	10 mg
lysine hydrochloride	15 mg
menaquinone 7	.03 mg
proline	15 mg
taurine	15 mg

Other Ingredients (Excipients)

Acacia

calcium phosphate

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Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
d-alpha-tocopherol
fractionated coconut oil
glycerol
Guar Gum
hydrolysed maize starch
lecithin
liquid glucose
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
purified water
silicon dioxide
sodium ascorbate
sucrose

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